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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,852	07/03/2002	Jurgen Marki	GKS-101.0(7911/83687)	1442
24628	7590	01/06/2006	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			NOAKES, SUZANNE MARIE	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 01/06/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,852

Applicant(s)

MARKI ET AL.

Examiner

Suzanne M. Noakes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-23-2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>12-13-2005</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9-23-2005</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status of the Claims

1. Claims 21 and 27 are pending and under examination. The amendments filed September 23, 2005 are acknowledged.

Drawings

2. The drawings were received on September 23, 2005. These drawings are accepted by the examiner.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on September 23, 2005 has been considered by the examiner.

Withdrawal of Rejections/Objections

4. The objection to the specification is withdrawn because: (a) Applicants have submitted an abstract of the disclosure and (b) Applicants have amended the layout of the specification to comply with the guidelines provided in 37 CFR 1.77(b).
5. The rejection of claims 21 and 27 under 35 U.S.C. 101 are withdrawn in view of the amendment to the claims reciting isolated.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 21 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The details of the rejection can be found in Sections 10-11 of the previous Office action.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Söhngen et al. (1997 - Cited on the IDS submitted on 18 July 2003).

Response to Arguments

35 USC § 102

9. Applicant's arguments filed September 23, 2005 have been fully considered but they are not persuasive. Applicants traverse the rejection and contend that Söhngren et al. do not teach the isolation and purification of homogenous subunits of KLH1 but only an analysis to determine the formerly unknown subunit organization of KLH1.

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Furthermore, it is reasoned that the way in which Söhhngren et al. conducted their experiments, e.g. treating whole KLH1 by limited proteolysis in order to separate each domain of KLH1 into each of its respective a-h domains, would necessarily result in fragments which would represent a mixture of different sequences that were not homogeneous or highly purified.

The examiner respectfully disagrees on the first point, that Söhhngren et al did not isolate the respective subunits. Isolation is separate from purification, and purification is not at issue because it is not stated in the claims. Isolated is deemed as being taken out of its natural state, thus a skilled artisan need only break open a cell which contains whole KLH (e.g. KLH1 and KLH2) in order to “isolate”. Because the claim possesses the comprising language, this would reasonably meet the limitations. And it is in this similar analysis that Söhhngren et al. do teach an isolated haemocyanin. Söhhngren et al. teach the separation of the subunits of KLH1, the limitation of isolation need only be taken from its natural state, or that of whole KLH1, and Söhhngren et al. have convincingly performed this task as evidenced by the SDS-Page gel and N-terminal mass spectrum data of the isolated domains. The issue is not whether a homogeneous mixture of, for instance, domain h (SEQ ID No: 73) has been homogeneously isolated because this limitation is again not in the claim, although a skilled artisan would easily recognize by the SDS-Page gel on p. 608, that a single band represents a highly purified/homogenous mixture. Söhhngren et al. also point to this fact by sequencing the N-terminus of each domain they isolated, and this is presented on p. 607, Table 3. The data presented in this table details N-terminal sequence analysis of the isolated

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domains from KLH1 which appear on the gels on p. 607. Upon comparing the N-terminal sequences against the ones presented in the claims, specifically SEQ ID Nos: 41 (domain c), 42 (domain d), 71 (domain f), 72 (domain g) and 73 (domain h), in each instance the isolated domains are missing the first 4-8 amino acids when compared to each of the comparable sequences taught by Applicant. Hence, Söhngrén et al. do not teach, for instance, a polypeptide/protein comprising SEQ ID No: 73, but they do teach what appears to be homogeneous domains that are *fragments*, which is a limitation of the claimed invention. In regards to the limitation of claim 27, in that the polypeptide is recombinant, in the absence of all other data and limitations (e.g. a glycosylated, fully active polypeptide) the fact that it is recombinantly produced does not necessitate novelty.

35 USC § 112 1st Paragraph – Written Description

10. Applicant's arguments with respect to the rejection of claims 21 and 27 under 35 U.S.C. 112 - written description, have been fully considered but they are not persuasive. Applicants reason that there is no mention that that fragments must possess the same immunological characteristics of the full length KLH1, just that of one of the domains and that a skilled artisan would be able to determine this by using immunoelectrophoresis which is present in the examples of the application and also in the prior art. As such, the situation is different than that of *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 which were drawn to making "hoped for" inventions. Furthermore,

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Applicant's, because they are in possession of the full length recombinant SEQ ID No: 73, were by *de facto* thus in possession of fragments thereof which can be obtained by deleting amino acids very easily, and that the activity would be retained (and could once again be assessed by immunoelectrophoresis).

In the first instance, the examiner sees no difference between *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 and their "hoped for" inventions and the instant case.

Fragments of a domain can constitute anything from two amino acids upto one amino acid short of the full length protein. The prior art provides no guidance nor does the specification as to what exactly the immunological property of the domain protein is versus the full length KLH1, and thus how is it be known if a fragment has any activity whatsoever if Applicant does not show possession of said fragment(s). The only way, as stated on p. 29, is for a skilled artisan to experiment in order to determine this. As stated in the previous Office action, *Vas-Cath Inc. V. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." because conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods of making the claimed invention.

New Rejections/Objections

Claim Objections

11. Claim 21 is objected to because of the following informalities: The claim is dependent upon a non-elected claim. Applicant is required to rewrite this claim in an independent format. Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 21 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (Micron. 1995. Vol. 26, No. 3, pp. 201-221). Harris et al. teach the isolation of KLH1 from KLH2 from *Megathura crenulata*, which is the organism that the present invention/polypeptides were isolated (initially) from. Both of these subunits are in their full lengths (e.g. possess all of their domains) and are shown on a native page gel on p. 207, Figure 5. The claims are anticipated because the claim language is open so reads upon the full length KLH1 and, by all comparable data, the invention now claimed and the protein of the prior art are the same or equivalent protein because the genus and species of bacteria are identical, the relative molecular weight of the protein isolated in the gel is identical. In addition, the protein has the same or equivalent amino acid

sequence whether the amino acid sequence is known or not, as the amino acid sequence is an inherent characteristic of a protein or polypeptide.

Conclusion

14. No claim is allowed.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SMN
27 December 2005



ROBERT A. WAX
PRIMARY EXAMINER